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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
AHMED, SHEEBA	
ART UNIT	PAPER NUMBER
1773	12

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/827,887	CLAUDE ET AL.	
	Examin r	Art Unit	
	Sheeba Ahmed	1773	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2003 has been entered.

Response to Amendment

2. Amendments to claims 33, 38, and 41 have been entered in the above-identified application. **Claims 33-41 are pending.**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 33-36, 38, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trotta (US 5,620,649) in view of Chabrecek et al. (US 6,447,920 B1).

Trotta discloses balloon catheters wherein the balloon comprises a pair of first layers made of a flexible material and a second layer positioned between the first layers

and comprises a vinylic polymer having functional groups chemically bonded to the first layers ***(the first layers disclosed by Trotta correspond to the first and second layers of the claimed invention and the second layer disclosed by Trotta corresponds to the covalently bonded functionality of the claimed invention)*** (Column 2, lines 8-13). The functional groups, which are found on the vinylic polymers, include carboxylic acid ***(thus meeting the limitations of claim 36)*** (Column 2, lines 29-35). As is conventional, the balloon catheter comprises an inflation lumen ***(which is an elongated shaft as seen in Figure 1 and thus meeting the limitations of claim 38)*** provided for fluid inflation and deflation of the balloon. The first layers may be formed of nylon and the second (bonding) layer may be formed of a modified polyethylene resin having pendant carboxylic acid groups such that a covalent bond may be formed between the second layer and the first (outer) layers through the carboxylic acid groups (Column 4, lines 17-44).

Trotta does not teach that the second layer has a thickness of about 10 to 150 nanometers.

However, Chabrecek et al. disclose coated biomedical devices having a bulk material coated with covalently bonded hydrophilic surface coating provided by applying unsaturated hydrophilic macromonomers and initiator radicals and polymerizing said macromonomers on the surface of the bulk material (Column 1, lines 1-55). The coatings may be applied by immersion, dipping spraying, spreading, pouring, or vapor deposition. The coating thickness can be controlled to obtain specific properties and the

thickness can be controlled to be from 0.001 *(equivalent to 1 nm)* to 100 mm (Column 23, lines 10-60).

Accordingly, it would have been obvious to one having ordinary skill in the art to optimize the thickness of the second layer or the covalently bonded functionality taught by Trotta given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the solution and further given that Chabrecek et al. specifically teach that the coating thickness of a hydrophilic coating on a biomedical device can be controlled to obtain specific properties and the thickness can be controlled to be from 0.001 *(equivalent to 1 nm)* to 100 microns. Furthermore, the determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see MPEP 2113.* In this case, the product (i.e., the balloon catheter) is the same despite the process limitation of plasma polymerizing the functionalized layer.

4. Claims 33-37 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhong (US 6,048,620) in view of Chabrecek et al. (US 6,447,920 B1).

Zhong discloses balloon catheters for angioplasty (Column 1, lines 25-26) wherein at least the balloon part is provided with a coating comprising a polymer having organic acid functional groups and a crosslinking agent having functional groups

capable of reacting with organic acid groups wherein the coating is applied, dried and then further coated with a hydrophilic polymer having organic acid functional groups such that the hydrophilic polymer becomes bonded to the polymer of the first coating composition through the crosslinking agent ***(the balloon part disclosed by Zhong corresponds to the second layer of the claimed invention, the first coating disclosed by Zhong corresponds to the covalently bonded functionality of the claimed invention and the second coating disclosed by Zhong corresponds to the first coating of the claimed invention)*** (Column 3, lines 15-30). Examples of organic acid groups include carboxylic acid groups (Column 4, lines 53-56). Examples of the first coating composition include acrylic copolymer dispersions ***(thus meeting the limitations of claims 36 and 37)*** (Column 5, lines 30-33).

Zhong et al. does not teach that their first coating has a thickness of about 10 to 150 nanometers.

However, Chabrecek et al. disclose coated biomedical devices having a bulk material coated with covalently bonded hydrophilic surface coating provided by applying unsaturated hydrophilic macromonomers and initiator radicals and polymerizing said macromonomers on the surface of the bulk material (Column 1, lines 1-55). The coatings may be applied by immersion, dipping spraying, spreading, pouring, or vapor deposition. The coating thickness can be controlled to obtain specific properties and the thickness can be controlled to be from 0.001 *(equivalent to 1 nm)* to 100 mm (Column 23, lines 10-60).

Accordingly, it would have been obvious to one having ordinary skill in the art to optimize the thickness of the first coating or the covalently bonded functionality taught by Zhong et al. given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the solution and further given that Chabrecek et al. specifically teach that the coating thickness of a hydrophilic coating on a biomedical device can be controlled to obtain specific properties and the thickness can be controlled to be from 0.001 *(equivalent to 1 nm)* to 100 microns. Furthermore, the determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see MPEP 2113.* In this case, the product (i.e., the balloon catheter) is the same despite the process limitation of plasma polymerizing the functionalized layer. All limitations of claims 33-37 are disclosed in the above reference.

5. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trotta (US 5,620,649) in view of Chabrecek et al. (US 6,447,920 B1) and Zhong (US 6,048,620).

Trotta and Chabrecek et al., as discussed above, do not disclose that the first layer (which corresponds to the first layer of the claimed invention) is made of polytetrafluoroethylene.

However, Zhong teaches that the materials used to make a balloon catheter include polytetrafluoroethylene, nylons, PE, PP, PVC and other resins (Column 8, lines 44-55). Zhong shows that polytetrafluoroethylene and nylon are equivalent structures known in the art. Therefore, because these two resins were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute polytetrafluoroethylene for nylon.

6. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trotta (US 5,620,649) in view of Chabrecek et al. (US 6,447,920 B1) and Okuda et al. (US 6,053,939).

Trotta and Chabrecek et al., as discussed above, do not disclose that the first layer (which corresponds to the first layer of the claimed invention) has a node and fibril microstructure.

However, Okuda et al. teach that a material having a nodes and fibril microstructure has excellent biocompatibility (Column 1, lines 11-19).

Accordingly, it would have been obvious to one having ordinary skill in the art to replace the nylon outer layer disclosed by Trotta with a material having a nodes and fibril microstructure given that Okuda et al. specifically teach that such a microstructure provides excellent biocompatibility.

Response to Arguments

7. Applicant's arguments with respect to claims 33-41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheeba Ahmed whose telephone number is (703)305-0594. The examiner can normally be reached on Mondays and Thursdays from 8am-6pm.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)306-5665.

Sheeba Ahmed
Sheeba Ahmed
September 3, 2003